Hepatitis C (Chronic, Acute)

Disease Plan

Quick Links

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Questions about this disease plan?

Contact the Utah Department of Health Bureau of Epidemiology: 801-538-6191.

✓ CRITICAL CLINICIAN INFORMAITON: ACUTE AND CHRONIC HCV

Clinical Evidence

Signs/Symptoms

- Acute infection with HCV is often asymptomatic (~80% of cases) or mild; therefore, it is uncommon for people to be diagnosed with HCV infection in the acute stage.
    - If symptoms do occur, they begin about seven weeks after infection and can include: jaundice, fatigue, dark urine, abdominal pain, loss of appetite, and nausea.
- With chronic infection, people are asymptomatic during the first decade or two of infection. Some patients may intermittently experience a range of symptoms, including fatigue, headache, joint aches, muscle aches, nausea, jaundice, loss of appetite, and/or abdominal pain.

Period of Communicability

- Anyone with a positive test for anti-HCV antibody is considered infectious until ruled out by negative HCV detection tests.
- The virus can usually be detected by the presence of viral RNA in an infected person's blood within 1-3 weeks after the initial exposure.

Incubation Period

- The incubation period for HCV ranges from two weeks to six months, with an average incubation period of 6-7 weeks.

Mode of Transmission

- Blood to blood transmission
- Currently, the highest risk of transmission is through sharing drug injection equipment.

Laboratory Testing

Type of Lab Test	Also Known As	Type of Specimens	Collection Timing
HCV RNA	PCR, NAAT, NAT, Viral Load	Serum or plasma	≥2 weeks after suspected exposure
HCV Antigen (when available)	HCV Ag	Serum or plasma	≥2 weeks after suspected exposure
HCV Antibody	Anti-HCV, HCV Ab	Serum or plasma	≥2 weeks after suspected exposure
HCV Genotype	Genotype by PCR	Serum or plasma	≥2 weeks after suspected exposure

Treatment Recommendations

Type of Treatment

- Direct-acting antivirals (DAAs)
- Most new DAAs are pangenotypic and a simplified treatment algorithm can be found here.

Prophylaxis

There is currently no post-exposure prophylaxis for HCV.

Case and Contact Management

Isolation of Case: None
Hospital: Standard precaution
Quarantine: None
Contact Management

- Drug use partners, specifically injection drug use, should be tested for hepatitis C and linked to care.

Infection Control Procedures

- Standard precautions

✓ WHY IS HEPATITIS C IMPORTANT TO PUBLIC HEALTH?

Hepatitis C virus (HCV) infection is a serious disease that can result in long-term health problems, including liver damage, liver failure, liver cancer, or even death. It is the leading cause of cirrhosis and liver cancer and the most common reason for liver transplantation in the U.S. Approximately 15,000 people die every year from HCV-related liver disease. It affects a diverse proportion of the population because prior to its identification, it had the opportunity to spread with little control through blood and organ tissue during transfusion and tissue transplant. Most individuals are unaware of their HCV infection status, which increases the probability of developing long-term health problems. Public health works to control HCV by increasing HCV awareness in the community, providing testing recommendations and education. With the recent advent of highly effective treatments that can cure many persons with chronic HCV infection, public health has a role in assessing the distribution and characteristics of persons who may be in need of treatment.

✓ DISEASE AND EPIDEMIOLOGY

Clinical Description

Symptoms – Acute

Initial infection with HCV is often asymptomatic (~80% of cases) or mild; therefore, it is uncommon for people to be diagnosed with HCV infection in the acute stage. If clinical illness does occur, symptoms begin about seven weeks after infection and can include: jaundice, fatigue, dark urine, abdominal pain, loss of appetite, and nausea. About 15-25% of HCV-infected individuals are able to clear the infection without treatment; the rest develop chronic infection. Hepatitis C is a disease with varying rates of progression. In general, however, its course is slowly progressive.

Symptoms – Chronic

Most people are asymptomatic during the first decade or two of chronic HCV infection. Some patients may intermittently experience a range of symptoms, including fatigue, headache, joint aches, muscle aches, nausea, jaundice, loss of appetite, and/or abdominal pain.

For many people with chronic hepatitis C, signs and symptoms appear only when liver disease is advanced. Almost 70% of those with chronic HCV infection develop chronic liver disease, a situation in which the virus damages the liver. The damage may progress to severe disease, including cirrhosis, liver cancer, and liver failure.

Severe disease or cirrhosis symptoms include fatigue, muscle weakness, poor appetite, nausea, weight loss, itching, dark urine, fluid retention, and abdominal swelling.

Causative Agent

HCV is a spherical, enveloped, single-stranded RNA virus belonging to the Flaviviridae family and Hepacivirus genus. HCV is related to hepatitis G, dengue, and yellow fever viruses. HCV can produce at least 10 trillion new viral particles each day. Six major HCV genotypes and numerous subtypes have been identified.

Genotypes

The major HCV genotype worldwide is genotype 1, which accounts for 40-80% of all isolates.

Figure 1: HCV Genotypes and Subtypes

	Genotype 1	Genotype 2	Genotype 3	Genotype 4	Genotype 5	Genotype 6
Subtypes	a, b, c	a, b, c, k	a, b, k	a	a	a, b, d, g, h, k
U.S. Prevalence	70%	16%	12%	1%	<1%	1%

Estimated U.S. Genotype (all subtypes) prevalence, as described in "Distribution of HCV genotypes in a diverse U.S. integrated health care population." J Med Virol. 2012 Nov;84(11):1744-50. doi:.1002/jmv.23399.

- Genotypes 1a and 1b are most prevalent in the U.S. and worldwide.
    - HCV genotype 1, particularly 1b, does not respond to therapy as well as genotypes 2 and 3. Recent HCV treatments have increased the response rate to genotype 1 therapy.
    - Genotype 1 also may be associated with more severe liver disease.
- Genotypes 2 and 3 are also found worldwide. However, in the U.S., they account for a minority of infections.
- Genotype 4, 5, and 6 are found worldwide, but are uncommon in the U.S. The largest proportions of genotypes 4 and 5 occur in lower-income countries, primarily in Africa. Genotype 6 is most prevalent in Vietnam, Cambodia, and the Philippines.

Differential Diagnosis

The major conditions that can be confused clinically with **acute hepatitis C** include:

- Acute hepatitis A and B
- Drug-induced hepatitis
- Alcoholic hepatitis
- Autoimmune disorders

The major conditions that can be confused clinically with **chronic hepatitis C** include:

- Autoimmune hepatitis
- Chronic hepatitis B and D
- Alcoholic hepatitis
- Non-alcoholic steatohepatitis (fatty liver)
- Sclerosing cholangitis
- Wilson's disease
- Alpha-1-antitrypsin-deficiency-related liver disease
- Drug-induced hepatitis

Laboratory Identification

Anti-HCV antibody (total antibody) testing is recommended for routine screening of asymptomatic persons based on their risk for infection, or based on a recognized exposure. For such persons, testing for HCV infection should include the use of an FDA-cleared test for antibody to HCV.

Persons tested for HCV infection and determined to be anti-HCV positive should be evaluated (by referral or consultation, if appropriate) for the presence of active infection, presence or development of chronic liver disease (CLD), and possible treatment. Nucleic acid testing, including reverse transcriptase polymerase chain reaction (RT-PCR) to detect HCV RNA (viral load), is necessary to confirm the diagnosis of current HCV infection, and an elevated ALT level is biochemical evidence of CLD (See Appendix A).

Several blood tests are performed to test for HCV infection (See Appendix B). Appendix B is data entry guidance – it will help investigators interpret the various tests. These tests can be characterized into two categories, anti-HCV antibody tests and HCV detection test.

Anti-HCV antibody tests

- Screening tests for total antibody to HCV (anti-HCV)
    - Enzyme immunoassay (EIA)
    - Enhanced chemiluminescence immunoassay (CIA)

HCV detection test

- Qualitative tests to detect presence or absence of virus (HCV RNA polymerase chain reaction [PCR])
- Quantitative tests to detect amount (titer) of virus (HCV RNA PCR)
- Genotype testing

Anti-HCV antibody can be detected as early as 4-10 weeks after infection and can be detected in >97% of persons by six months.

False positive anti-HCV antibody tests appear more often when persons at low risk for HCV infection (e.g., blood donors) are tested. Therefore, it is important to follow-up all positive anti-HCV antibody tests with an HCV detection test to establish current infection.

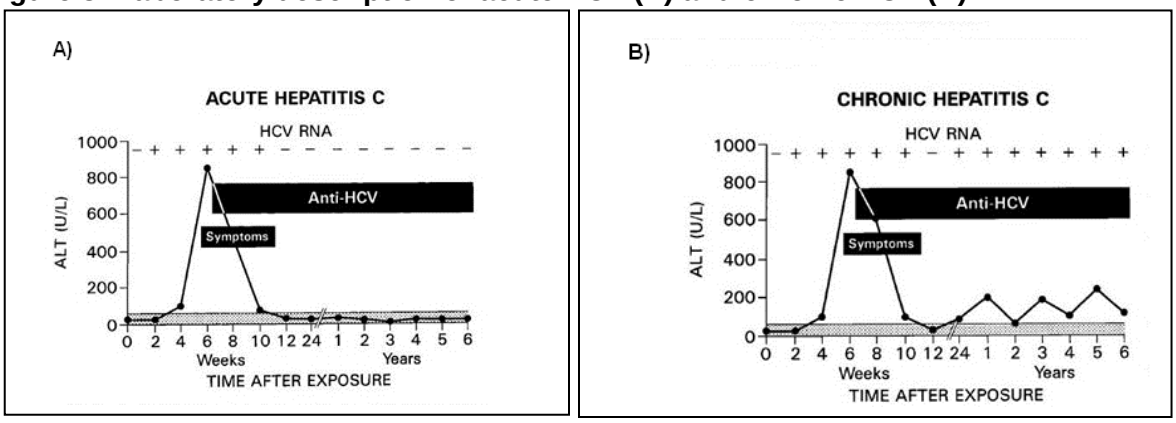
Figure 2: Laboratory test interpretation

Anti-HCV Antibody	Qualitative PCR	Quantitative PCR	Genotyping	Testing Interpretation
+	-	<n* and/or not detected	Negative or Indeterminate	Previously exposed, not currently infected or false positive antibody
+	+	Quantified viral load	Genotype Identified	Current Infection

*<n will be dependent upon the detectable range of laboratory methodology used

Persons with early HCV infection might not yet have developed anti-HCV antibody levels high enough that the test can measure it (termed the “window” period). In addition, some persons might lack the immune response necessary for the test to work well. In these persons, further testing such as PCR for HCV RNA may be considered. HCV RNA appears in blood and can be detected as early as 2-3 weeks after infection.

Figure 3: Laboratory description of acute HCV (A) and chronic HCV (B)



In acute HCV, liver enzymes may be elevated up to, and in excess of, 10 times greater than normal values. This elevation is typically observed after two weeks of infection and will return to normal levels within 12 weeks. Fifteen to 25% of acute infections will self-resolve; the majority of acute cases (75-85%) will progress to chronic HCV infection.

It is common for patients with chronic HCV to have liver enzyme levels that go up and down, with periodic returns to normal or near normal levels. Liver enzyme levels can remain normal for over a year despite CLD.

Most patients with chronic hepatitis C have a viral load between 100,000 ($1X10^5$) and 10,000,000 ($1X10^7$) copies per mL. Expressed as IU, these averages are 50,000 to 5 million IU.

Viral levels as measured by viral load do not correlate with hepatitis severity or with a poor prognosis (as in HIV infection). However, viral load inversely correlates with the likelihood of a response to antiviral therapy (e.g., cases with low initial viral load levels have a better therapeutic outcome than cases with high initial viral load levels.)

Utah Public Health Laboratory (UPHL): UPHL has the ability to perform anti-HCV antibody and HCV NAAT on collected specimens.

High-Risk Group Screening Recommendations

"High-risk" is defined as persons with a current or past history of injection drug use, and persons who had a blood transfusion prior to 1992. Repeat screening for high-risk persons is recommended annually only for persons who have had continued injection drug use since a prior negative screening test.

The determination of "high-risk for HCV" is identified by the primary care physician or practitioner who assesses the patient's history, which is part of any complete medical history, typically part of an annual wellness visit, and considered in the development of a comprehensive prevention plan.

Birth Cohort – People Born 1945-1965

In 2012, the CDC issued a recommendation to test everyone born from 1945-1965 ("baby boomers") for HCV. While anyone can get HCV, up to 75% of adults infected with hepatitis C were born from 1945-1965. Baby boomers are five times more likely to have HCV than other adults. This

population was thought to have been infected in the 1970's and 1980's when HCV rates were highest. This was before education initiatives were implemented and the transmission risks of the virus were widely known. This recommendation is intended to encourage this population to get screened to know their HCV status and refer them to care. The longer people live with undiagnosed and untreated HCV, the more likely they are to develop serious, life-threatening liver disease.

Pregnancy

The CDC recommends universal one-time testing for all pregnant women for each pregnancy.. Approximately six of every 100 infants born to HCV-infected women become infected. This infection occurs predominantly during or near delivery, and no treatment or delivery method—such as cesarean section—has been demonstrated to decrease this risk. The risk of transmission is increased by the presence of maternal HCV viremia at delivery, and is 2-3 times greater if the woman is co-infected with HIV. HCV has not been shown to be transmitted through breast milk, although HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding. Children born to HCV-positive mothers should be tested for HCV infection and, if positive, evaluated for the presence of chronic liver disease.

HIV Infection

All persons with HIV infection should undergo serologic testing for HCV. People with HIV who have ongoing risk factors for HCV infection should be routinely screened. The progression of liver disease is more rapid in HIV/HCV co-infected persons, and the risk for cirrhosis is nearly twice that of persons with HCV infection alone. Co-infected persons receiving HIV antiviral regimens are now being treated for HCV after their CD4+ cell counts increase, optimizing their immune response.

Healthcare Personnel

After a needle stick or sharps exposure to HCV-positive blood, the risk of HCV infection is approximately 1.8% (range: 0%–10%). Although a few cases of HCV transmission via blood splash to the eye have been reported, the risk for such transmission is expected to be very low.

Avoiding occupational exposure to blood is the primary way to prevent transmission of bloodborne illnesses among healthcare personnel. All healthcare personnel should adhere to Standard Precautions. Depending on the medical procedure involved, Standard Precautions may include the appropriate use of personal protective equipment (e.g., gloves, masks, and protective eyewear). In the event of an occupational exposure, the healthcare personnel should contact their employee health representative, follow OSHA bloodborne exposure recommendations, and be tested according to the CDC bloodborne infectious disease guidance.

There are no CDC recommendations to restrict a healthcare worker who is infected with HCV. The risk of transmission from an infected healthcare worker to a patient appears to be very low. All healthcare personnel, including those who are infected with HCV, should follow strict aseptic technique and Standard Precautions, including appropriate hand hygiene, use of protective barriers, and safe injection practices.

Treatment

The landscape of treatment for HCV infection has evolved substantially since the introduction of highly effective HCV protease inhibitor therapies in 2011. The pace of change is expected to

increase rapidly, as numerous new drugs with different mechanisms of action will likely become available over the next few years. To provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens, the Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD), in collaboration with the International Antiviral Society–USA (IAS–USA), developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for HCV management. The IAS–USA provided the structure and assistance to sustain the process that represents the work of leading authorities in hepatitis C prevention, diagnosis, and treatment in adults, from 2013 to 2015.

The American Association for the Study of Liver Disease/Infectious Diseases Society of America (AASLD/IDSA) Guidance on Hepatitis C (www.hcvguidelines.org) addresses management issues ranging from testing and linkage to care, the crucial first steps toward improving health outcomes for HCV-infected persons, to the optimal treatment regimen in particular patient situations. Recommendations are based on evidence and are rapidly updated as new data from peer-reviewed evidence become available. For each treatment option, recommendations reflect the best possible management for a given patient and a given point of disease progression. Recommendations are rated with regard to the level of the evidence and strength of the recommendation. The guidance should be considered a "living document" in that the guidance will be updated frequently as new information and treatments become available. This continually evolving report provides guidance on FDA-approved regimens. At times, it may also recommend off-label use of certain drugs or tests or provide guidance for regimens not yet approved by FDA. Readers should consult prescribing information and other resources for further information. Of note, the choice of treatment may, in the future, be further guided by data from cost-effectiveness studies.

Most new DAAs are pangenotypic and a simplified treatment algorithm can be found here.

Treatment duration

Treatment duration depends on genotype, liver health, previous treatment and other factors. Most treatments range from 8-24 weeks. The goal of treatment is to eliminate HCV RNA and achieve a sustained virologic response (SVR). An SVR has been demonstrated to result in a 97 to 100 percent chance of remaining HCV RNA negative after long-term follow-up. Individuals who achieve SVR are considered cured of the HCV infection. The definition of SVR is an absence of HCV RNA 24 weeks after treatment.

Treatment response and success

Each treatment has a different response rate and depends on several factors, including: genotype, race, age, weight, extent of liver damage, viral load, HIV Infection, previously treated or not, alcohol use, length of infection, and adherence.

A person reaching SVR after completing treatment suggests that HCV infection has been cured. SVR can result in decreased cirrhosis and complications of liver disease, decreased rates of liver cancer (hepatocellular carcinoma), and decreased mortality. Most new medications are showing a SVR of 93-100%.

Treatment Side Effects

Each treatment has potential for a variety of adverse effects. However, most of the new medications that are interferon- and ribavirin-free seem to be easily tolerated with very few minor side effects including headache, fatigue, and insomnia.

Pegylated or standard interferon: fatigue, flu-like symptoms, mood changes, drop in platelet count, drop in white blood cell count, drop in neutrophil count, loss of appetite, nausea or change in bowel habits, weight gain or weight loss, hair loss, changes in thyroid function, increase in blood sugar level, and insomnia may be associated with these medications.

Ribavirin: Drop in red blood cell count, sore throat, cough, shortness of breath, rash, and birth defects may be associated with use of ribavirin.

Clinical Trials

Research facilities conduct clinical trials on hepatitis medications and are often looking for individuals to participate. For further information on current trials and qualifications, visit www.clinicaltrials.gov. Local agencies that have a history of HCV Medication Clinical trials include: The University of Utah Medical Center (http://healthcare.utah.edu/clinicaltrials) and Jean Brown Research (https://www.jbrclinicalresearch.com) or contact the UDOH Bureau of Epidemiology, Prevention Treatment and Care Program (PTCP) at 801-538-6191 for additional resources.

Case Fatality

In the U.S., HCV is a contributing cause of death in approximately 15,000 people per year. According to the CDC, death certificates listing HCV as a cause of death have increased from 16,627 in 2010 to 19,368 in 2013.

Reservoir

Humans are the only known reservoir of HCV.

Transmission

HCV is a bloodborne pathogen that is predominantly spread via exposure to contaminated blood or blood products. Currently, the highest risk of transmission is sharing needles or syringes to inject drugs. Continued injection drug use increases the risk of HCV infection. Studies have shown up to a 33% seroprevalence among 18-30 year-old injection drug users (IDUs) and increases substantially (70-90%) among older and former IDUs.

Blood transfusions pose an extremely limited risk now. But, for patients who received a blood transfusion prior to June 1992, the risk of infection was approximately 1.5% per transfusion recipient.

Sexual transmission of HCV is very low, but can occur. The risk of sexual transmission increases with multiple partners, co-infection with HIV, MSM, anal sex, and any other sexual activity where blood may be exchanged.

Other potential risks for transmission include:

- Long-term hemodialysis
- Sharing straws for intranasal drug use
- Vertical (mother to infant) transmission (the risk of perinatal transmission is estimated to be about 5%, although if the mother is co-infected with HIV, the risk may be approximately 15–25%)
- Occupational blood exposure (the risk of occupational exposure for healthcare workers has been estimated to be 1.8% per incident of hollow-bore needle stick exposure to HCV-infected blood)
- Various medical procedures with non-sterile equipment (including dental)
- Tattooing or body piercing with non-sterile equipment

HCV is not spread through casual contact, kissing, sneezing, hugging, and sharing glasses or utensils, or breast milk.

Susceptibility

HCV infection occurs among persons of all ages. The highest incidence of acute HCV infection (new cases) occurs among persons aged 20-40 years. Cases may be infected by more than one genotype, but this is rare. Patients can be treated for one genotype, and be re-infected via the same or another genotype.

Incubation Period

The incubation period for HCV ranges from two weeks to six months, with an average incubation period of 6-7 weeks.

Period of Communicability

Communicability of HCV is variable; anyone with a positive test for anti-HCV antibody should be considered infectious until ruled out by negative HCV detection tests. The virus can usually be detected by the presence of viral RNA in an infected person’s blood within 1-3 weeks after the initial exposure. The degree of correlation between quantity of circulating virus and communicability is not clearly established.

Epidemiology

HCV has a worldwide distribution. In the U.S., an estimated 2.4 million people were infected with HCV during 2013-2016. The CDC estimates approximately 50,300 acute HCV cases (newly infected individuals) occurred in 2018. Prevalence is highest among groups with specific risk factors, especially IDUs, patients with hemophilia, on long-term hemodialysis, prison inmates, and people who received blood or organ products prior to June 1992.

Most of these newly reported cases are not people with new (acute) disease, but those with chronic infection who have been newly diagnosed. There remains a large population of undiagnosed people who were infected in the past. It is estimated that only 25% of individuals with HCV know they are infected.

✓ PUBLIC HEALTH CONTROL MEASURES

Public Health Responsibility

- To provide information to HCV-infected patients on the importance of medical evaluation, why continued care is needed, how to reduce disease progression, and to provide referrals to medical or supportive facilities for these services.
- To provide current treatment information and resources.
- To provide information to HCV-infected persons on how to prevent exposing others.
- To provide education to HCV-infected pregnant women on the importance of prenatal care and strategies to reduce the transmission risk to their child.
- To determine the incidence and prevalence of HCV in specific populations and geographic locations to help guide HCV prevention and education activities, and other public health interventions.
- To identify clusters of HCV cases or outbreaks.
- To investigate all suspect acute cases of disease, as explained in the investigation protocol below.
- To investigate individuals co-infected with HIV/AIDS or hepatitis B without evidence of previously documented investigation.
- To provide education to the general public, clinicians, and first responders regarding disease transmission and prevention.
- To identify sources of exposure and prevent further transmission.

Prevention

The goals of HCV prevention and control efforts are:

1) To reduce the incidence of new infections by reducing HCV transmission.
2) To reduce the risk of chronic liver disease in HCV-infected individuals through appropriate medical management and counseling by ensuring linkage to care.
3) To educate infected persons on how to care for themselves and how to avoid spreading infection to others.

Chemoprophylaxis

There is currently no post-exposure prophylaxis for HCV, although treatment is available for infected individuals.

Vaccine

There is currently no vaccine for HCV. It is recommended that HCV infected individuals receive hepatitis A and hepatitis B immunizations to prevent further liver disease. There are currently HCV vaccines under development; the progress of these vaccines can be monitored on the U.S. Food and Drug Administration website.

Isolation and Quarantine Requirements

Isolation: None.
Hospital: Standard Precautions.
Quarantine: None.

No restrictions except for exclusion from organ and blood donation.

✓ CASE INVESTIGATION

Reporting

All cases of HCV infection are reportable to public health.

Criterion for Reporting HCV acute and chronic

Criterion	Reporting
Laboratory Criteria for Reporting	
Antibodies to hepatitis C virus (anti-HCV)	S
Nucleic Acid Test (NAT) for HCV RNA positive	S
Positive test for hepatitis C antigen(s)*	S
Vital Records Criteria for Reporting	
Death certificate lists hepatitis C	S
Birth certificate lists birth mother as having hepatitis C	S
Other Criteria for Reporting	
Healthcare record contains a diagnosis of hepatitis C	S

Notes:
S = This criterion alone is sufficient to report a case.
*When and if a test for HCV antigen(s) is approved by FDA and available.

Clinical Descriptions

All HCV cases in each classification category below should be >36 months of age, unless known to have been exposed non-perinatally.

Acute or Chronic Clinical Criteria

- Illness with either jaundice, **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/L, **OR**
- Peak elevated total bilirubin levels (Tbili) ≥ 3.0 mg/dL, **AND**
- The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic HCV infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Illness can occur with or without discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain).

Laboratory Criteria

Confirmatory laboratory evidence:

- Positive hepatitis C virus detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing), **OR**
- A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)

Presumptive laboratory evidence:

- A positive test for antibodies to hepatitis C virus (anti-HCV)

Epidemiologic Linkage

No epidemiologic linkage is required for case classification.

Case Classification

Acute, confirmed

- A case that meets clinical criteria and has confirmatory laboratory evidence, **OR**
- A documented negative HCV antibody followed within 12 months by a positive HCV antibody test (anti-HCV test conversion) in the absence of a more likely diagnosis, **OR**
- A documented negative HCV antibody **OR** negative hepatitis C virus detection test (in someone without a prior diagnosis of HCV infection) followed within 12 months by a positive hepatitis virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis

Acute, probable

- A case that meets clinical criteria and has presumptive laboratory evidence, **AND**
- Does not have a hepatitis C virus detection test reported, **AND**
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months

Chronic, confirmed

- A case that does not meet OR has no report of clinical criteria, **AND**
- Has confirmatory laboratory evidence, **AND**
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months

Chronic, probable

- A case that does not meet **OR** has no report of clinical criteria, **AND**
- Has presumptive laboratory evidence, **AND**
- Has no documentation of anti-HCV or RNA test conversion within 12 months, **AND**
- Does not have an HCV RNA detection test reported

Criteria to distinguish a new case of HCV

A new acute case is an incident case that is over the age of 36 months and has not previously been reported meeting case criteria for chronic hepatitis C or for whom there is laboratory evidence of re-infection. Cases under the age of 36 months should be classified under the Perinatal HCV case classification unless the exposure mode is not perinatal (e.g., healthcare acquired).

A new probable acute case may be reclassified as confirmed acute if a positive HCV viral detection test is reported in the same reporting year. If evidence indicating resolution of infection is received

after a confirmed acute or confirmed chronic case has been reported to CDC, the case report does not need to be modified as it was a confirmed case at the time of initial report. However, negative HCV viral detection test results received on confirmed acute and chronic cases, subsequent to an initial positive result, should be appended to case reports, as feasible.

Evidence for re-infection may include a case of confirmed chronic HCV infection that has at least two sequential negative HCV viral detection tests reported, indicative of treatment initiation and sustained virologic response, followed by a positive HCV viral detection test. Under current treatment recommendations, those two negative tests should be at least three months apart, however, the timing may change as standard of care for HCV treatment evolves. Other evidence of reinfection should be considered, including a report of a new genotype on a case that has previously cleared a different genotype.

A new chronic case is a newly reported case that does not have evidence of being an acute case of HCV infection. A confirmed acute case may be classified as a confirmed chronic case if a positive HCV viral detection test is reported one year or longer after acute case onset. A confirmed acute case may not be reported as a probable chronic case (i.e., HCV antibody positive, but with an unknown HCV viral detection test).

Criterion for classification of HCV

	Acute				**Chronic**	
Criterion	**Confirmed**			**Probable**	**Confirmed**	**Probable**
Clinical Evidence						
Jaundice	O			O		
Total bilirubin >3.0 mg/dL	O			O		
ALT >200 IU/L	O			O		
The absence of a more likely diagnosis	N	N	N	N		
>36 months of age, unless known to have been exposed non-perinatally	N	N	N	N	N	N
Does not meet or has no report of clinical criteria					N	N
Laboratory Evidence						
Positive anti-HCV antibody				N		N
Positive NAT for HCV RNA test (including quantitative, qualitative, and genotype)	O				O	
Positive HCV antigen test	O				O	
Absence of a negative HCV viral detection test				N		N
A documented negative HCV antibody test result followed within 12 months by a positive HCV antibody or positive HCV viral detection test result		N				

A negative HCV viral detection test result followed within 12 months by a positive HCV viral detection test if not previously reported as having HCV infection			N			
Criteria to distinguish a new case						
Not previously reported as an acute case within one year	N	N	N	N	N	N
Not previously reported as a chronic case unless there is evidence of having cleared HCV infection since the initial report					N	N

Notes:
N = All "N" criteria in the same column are NECESSARY to classify a case. A number following an "N" indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the absence of criterion as a necessary component.
O = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case. A number following an "O" indicates that this criterion is only required for a specific disease/condition subtype.

Nosocomial Outbreaks

Nosocomial outbreaks are uncommon with hepatitis C, but could occur with lack of infection control. Contact UDOH for assistance with any suspect or confirmed nosocomial HCV outbreaks or occurrences.

Resolved infection: 'Treated and Cured' or 'Self Resolved'

Treated HCV infected patient

When a patient has completed HCV treatment and receives a negative HCV detection test ≥24 weeks after treatment (SVR), that individual is considered 'Treated and Cured.' 'Treated and Cured' individuals can become re-infected with HCV. When a 'Treated and Cured' individual is determined to be re-infected, as evident through a positive HCV detection test, the case will be treated as a new event and managed according to the investigation algorithm in Figure 4.

Untreated HCV infected patients

Individuals that are not known to have been treated, who through laboratory evidence, demonstrate negative results on an HCV detection test will be considered 'Self-resolved' after **two** negative HCV detection tests on different collection dates or collected on the same date, but tested using differing HCV detection laboratory methodologies. 'Self-resolved' individuals can become re-infected with HCV. When a 'Self-resolved' individual is determined to be re-infected, as evident trough a positive HCV detection test, the case will be treated as a new event and managed according to the investigation algorithm in Figure 4.

Case Investigation Process

All acute cases will be investigated (asymptomatic cases with documented seroconversion in the past 12 months, and cases with elevated ALT (>200 IU/L), Tbili (>3.0 mg/dL) and/or jaundice.

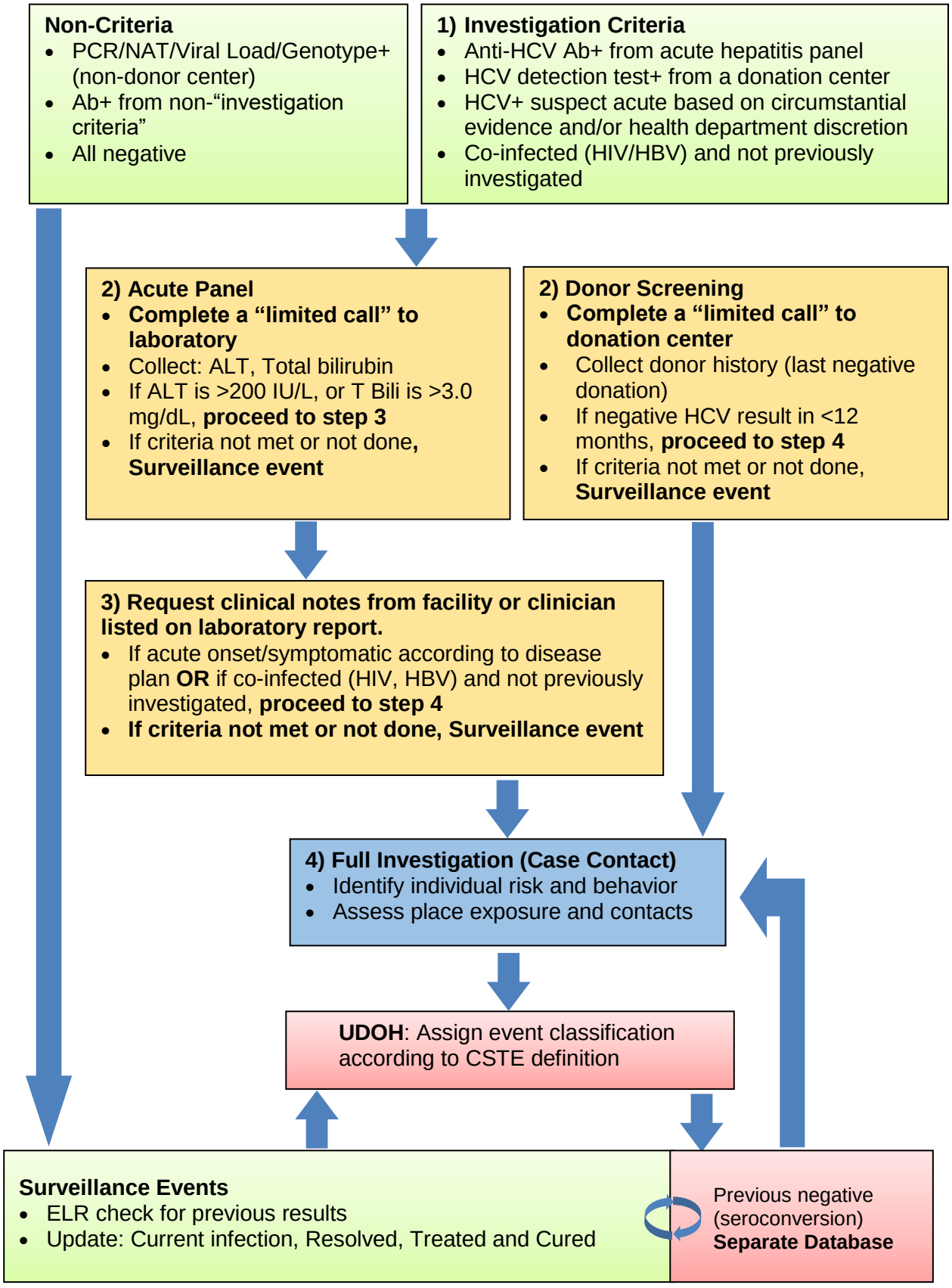
Chronic cases and cases that are determined not to be acute are considered surveillance events.

The HCV surveillance system is designed to focus investigator efforts on likely acute cases based on the first reported laboratory test. This is accomplished by first identifying likely acute cases based on the test type (e.g., acute hepatitis panel) or diagnostic facility (e.g., blood component donor facilities). Individuals that do not meet investigation criteria are not investigated. Individuals that are reported as HCV positive (either anti-HCV antibody or HCV detection test) from the likely acute categories have met investigation criteria and are investigated by one of two methods:

1) Individuals reported as HCV positive from a blood component donation center will have their last negative test date ascertained from the donor center. If the donor's last negative HCV test was less than 12 months from their HCV positive test, the donor will continue to meet investigation criteria and will be contacted by public health to assess exposure risks and provide education. If the donor was a first-time donor, or the last negative donation was greater than 12 months prior, the case will be considered a surveillance event with no further investigation given clinical criteria is not met.
2) Individuals reported from an acute hepatitis panel will have their ALT and/or total bilirubin (Tbili) requested from the reporting lab. If ALT is greater than 200 IU/L or Tbili is greater than 3.0 mg/dL, the case will continue to meet investigation criteria. Clinical information should be gathered to ascertain if there is/was jaundice present and to ensure there is not another more likely diagnosis that is contributing to clinical presentation. If the case meets acute case definition criteria, the case will be contacted by public health to assess exposure risks and provide education. If the acute HCV case definition criteria is not met (due to a more likely diagnosis), the case will be considered a surveillance event with no further investigation.

UDOH enhanced reports: UDOH receives an automated report providing ALT and Tbili from individuals identified as HCV positive from acute hepatitis panels at some medical facilities, as available. This information is entered into UT-NEDSS/EpiTrax to assist investigators. UDOH will continue to work with medical providers to expand the use of automated data collection to support investigational efforts.

Figure 4: Investigation Algorithm



Outbreaks

An outbreak is defined as:

- Two (2) or more cases of HCV clustered in time, **AND**
- At least one (1) confirmed case, **AND**
- At least one of the following:
    - A common exposure
    - Laboratory evidence of highly related viral sequences

Occasionally, a healthcare-associated outbreak may be identified by a single sentinel case, e.g., a frequent blood donor with no identified risk who has had contact with the healthcare system where parenteral exposure to blood or blood-contaminated products may have occurred. Investigation of such outbreaks can be quite complex and requires strong collaboration among involved parties and expert advice.

Identifying Case Contacts

Identification of case contacts for an acute case should focus on individuals that may have been exposed to the case's blood (e.g., sharing needles, sharing drug preparation equipment [i.e. spoons, cotton, syringes, water bottles], or tattoo equipment and supplies). Otherwise, encourage the case-patient to speak to people who may have been exposed to their blood since the time the case-patient was estimated to have been exposed, infected, or seroconverted.

Case Contact Management

Percutaneous and Mucosal Exposure to HCV Infection

Recommend baseline anti-HCV antibody testing and HCV detection test if indicated. If baseline testing is negative, recommend testing for anti-HCV antibody and ALT 4-6 months after exposure. Recommend HCV detection testing at 4-6 weeks if earlier diagnosis of HCV is desired. Reactive anti-HCV antibody tests should be confirmed with an HCV detection test to identify current infection. Contacts with a positive anti-HCV antibody and/or HCV detection test should be reported and investigated according to the HCV disease plan.

Pregnant women

Routine one-time screening for all pregnant women for each pregnancy is recommended. All HCV positive pregnant women should be reported for pregnancy surveillance and mothers should be provided resources/education for infant follow-up testing. In several studies, high maternal viral load and positive HCV-RNA are predictors for vertical transmission rate, as well as maternal co-infection with HIV. Co-infection with HIV both accelerates the clinical progression of HCV and increases the risk of perinatal HCV transmission from 5% (range, 3–8%) to 17% (range, 7–36%).

Infants born to HCV positive mothers

The American Academy of Pediatrics (AAP) recommends screening infants born to HCV- infected mothers. The AAP recommends that testing for anti-HCV antibodies be performed after 18 months of age, as passively acquired maternal antibodies can last up to 12 months. A negative HCV detection test strongly suggests that the infant is not infected, although a confirmatory re-test at least three months after the initial test is advised. A positive HCV detection test increases the post-test probability that the infant is infected with HCV.

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✓ VERSION CONTROL

January 5, 2015: This disease plan contains updated testing, treatment, and investigation processes and information. The major changes in the investigation process change the investigation criteria from age based investigation criteria to acute case investigation.

February 6, 2015: Updated plan with new CSTE position statement classification tables and narrative descriptions.

March 3, 2016: HCV disease plan workgroup updates. Complete guidance and investigation revamp. Chronic case definition included and shift to acute case investigation.

March 11, 2016: Added guidance for ‘Treated and Cured’ and ‘Self-resolved.’

March 13, 2019: Added Critical Clinician Information for chronic and acute hepatitis C.

January 2, 2020: Updated plan with new CSTE position statement classification tables and narrative descriptions. Updated investigation algorithm to reflect new CSTE position statement.

January 7, 2020: Added Clinical Description for acute and chronic HCV.

February 19, 2020: Updated ELR processing rules.

April 6, 2020: Updated links and formatting and included recommendation for testing of pregnant women.

✓ UT-NEDSS/EPITRAX Minimum/Required Fields by Tab

Demographic
- Age
- Area Code
- Birth Gender
- City
- County
- Date of Birth
- Ethnicity
- First Name
- Last Name
- Phone Number
- Race
- State
- Street
- Zip Code

Clinical
- Clinician First Name
- Clinician Last name
- Date Diagnosed
- Date of Death
- Diagnostic Facility (DF)
- DF State
- DF City
- DF County
- Died
- Disease
- Pregnant
- Does patient have jaundice?
- ALT (SGPT) results:
- ALT interpretation:
- Hepatitis B?, Date of diagnosis
- HIV/AIDS?, Date of diagnosis

Laboratory
- Collection Date
- Lab
- Organism
- Result Value
- Test Result
- Test Type
- Units
- Bilirubin results:
- ALT (SGPT) results:
- ALT interpretation:

Epidemiological
- None

Contacts
- None

Reporting
- Date first reported to public health

Administrative
- LHD investigation/intervention started
- State case Status
- Outbreak name
- Outbreak-associated

✓ Electronic Laboratory Reporting Processing Rules

Hepatitis C Rules for Entering Laboratory Test Results

The following rules describe how laboratory results reported to public health should be added to new or existing events in UT-NEDSS/EpiTrax. These rules have been developed for the automated processing of electronic laboratory reports, although they apply to manual data entry, as well.

Test-Specific Rules

Test specific rules describe what test type and test result combinations are allowed to create new morbidity events in UT-NEDSS/Epi-Trax, and what test type and test result combinations are allowed to update existing events (morbidity or contact) in UT-NEDSS/Epi-Trax.

Test Type	Test Result	Create a New Event	Update an Existing Event
Genotype by sequencing	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
PCR/Amplification	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Total Antibody	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Viral Load – Qualitative bDNA	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Viral Load – Qualitative RT- PCR	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Viral Load – Quantitative RT-PCR	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Western (Immuno) Blot	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes

Genotype 1a or 1b	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1b	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1c	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2b	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2c	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 3a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 3 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 4a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 4k	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes

Genotype 4 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 5 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6e	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6h	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6l	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Liver Function Tests (ALT, AST, bilirubin)	All	No	Yes

Whitelist Rules

Whitelist rules describe how long an existing event can have new laboratory data appended to it. If a laboratory result falls outside the whitelist rules for an existing event, it should not be added to that event, and should be evaluated to determine if a new event (CMR) should be created.

Hepatitis C virus Morbidity Whitelist Rule: Never a new case.

Hepatitis C virus Contact Whitelist Rule: Always added to contact.

Graylist Rule

We often receive laboratory results through ELR that cannot create cases, but can be useful if a case is created in the future. These laboratory results go to the graylist. The graylist rule describes how long an existing event can have an old laboratory result appended to it.

Hepatitis C virus Graylist Rule: If the specimen collection date of the laboratory result is 18 months before to seven days after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

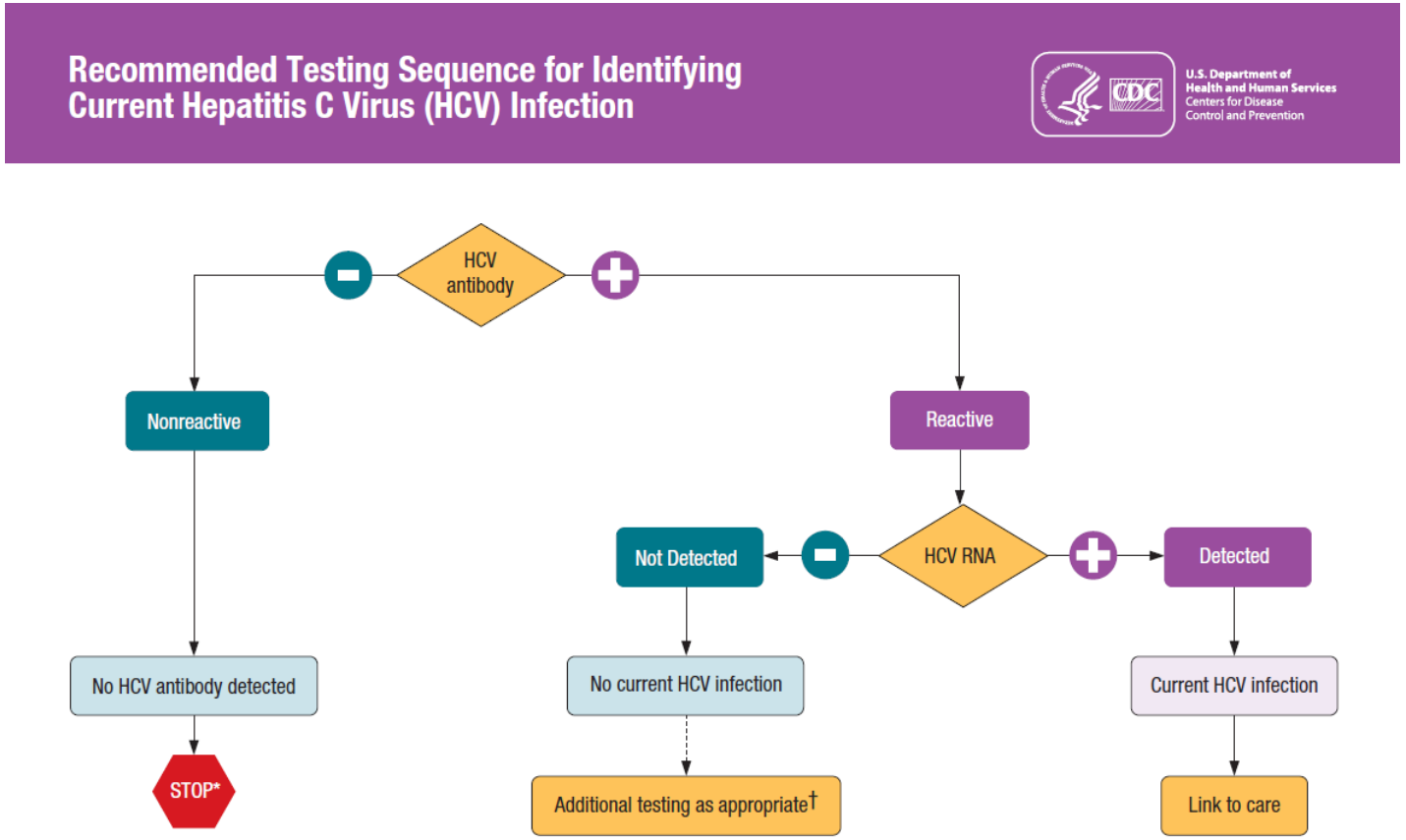
Liver function Graylist Rule: If the specimen collection date of the laboratory result is six months before to six months after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

Other Electronic Laboratory Processing Rules

If an existing event has a state case status of “not a case,” ELR will never add additional test results to that case. New labs will be evaluated to determine if a new CMR should be created.

✓ APPENDICES

Appendix A: HCV Testing Algorithm



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Appendix B: HCV Laboratory Report Guidance

Test Type	Total Ab (EIA, IFA, TRF, Etc.)	Western (Immuno) Blot (RIBA)	Viral Load	Genotype	ALT	AST	Bilirubin
Common Test Codes	HCV ab, HCVDA, hepatitis C ab, hepatitis C antibody, Ab S/CO, s/co	RIBA	PCR, NAT, NAAT, qualitative, quantitative	Genotype sequencing	• (ALT) alanine aminotransaminase • (AST) aspartate aminotransaminase • (Bilirubin), Tbili, Bili		
Reporter	Local hospitals, Cat-C, donor centers, reference laboratories	Reference laboratories	Reference laboratories, donation centers, some local hospitals	Reference laboratories	Local hospitals, some reference laboratories		
Results	Reactive, positive, equivocal, indeterminate, ≥11, reactive **HI, low** positive, reactive (number), low s/com, HI s/co	Positive, negative, reactive, non-reactive	Numbers, reactive, non-reactive, positive, negative, HI, detected, no detected, **<43****	Genotype 1a, 1b, 2a, 2b, 2c, 2d, 3a, 3b, 3c, 3d, 3e, 3f, 4a, 4b, 4c, 4d, 4e, 4f, 4g, 4h, 4i, 4j, 5a, 6a	Number	Number	Number
Units	None, IV, s/co	None	IU/mL, LOG IU/mL, Copies, copies/mL	None	U/L	U/L	mg/dL
Hints	All antibody tests are considered equivalent and must be confirmed by a more specific assay.	This lab test is not routinely used anymore, so it will be very rare to see one.	Tests that have numbers over 10,000 is a clue that it is a viral load.	Some laboratories do not differentiate between similar genotypes and will report both (e.g., 1a and 1b).	These three tests are components of clinical testing. They can be found in laboratory panels called: Liver Function Panel, Liver Function Test (LFT), and **Comprehensive Metabolic Panel (CMP).**		

**Viral loads may result <43, but state HCV RNA detected. This is a positive test. The quantity of IU was less than the test's sensitivity range.

Appendix C: Patient Education

Prevention and education include providing information on how the disease is transmitted, how to prevent spread of infection, how patients can protect themselves from other potential sources of liver damage, and available treatment options. Offer the information and support below to newly identified cases:

- Provide basic instruction on transmission of HCV and emphasize the need for ongoing medical evaluation. Treatment is available and effective, and the case should be referred to their healthcare provider for a discussion of treatment options.
- Discuss sexual transmission of HCV. Indicate that HCV may be transmitted during sex. Monogamous sexual partners are at lower risk of transmission than those with multiple partners. All contact with blood during sex should be avoided. Emphasize latex barrier protection as a way to prevent the spread of HCV, as well as a way to prevent exposure to and transmission of other pathogens.
- Discuss household transmission of HCV. Household transmission is rare, but to ensure that it does not happen, the case should not share razors, toothbrushes, nail clippers, or any other item that could be contaminated with blood.
- If the patient is a current injection drug user, provide referrals to drug treatment and needle exchange programs if the case needs, or wants, support to stop using. This will help prevent the spread to other individuals.
- Educate the case on the need to abstain from alcohol to help protect the liver. If a case needs, or wants, support to stop drinking, provide referrals to appropriate treatment or support services.
- Discuss medications that should be avoided (e.g., acetaminophen) as high doses can damage the liver. All cases should discuss medications (including over-the-counter medications), dietary supplements, and herbs with a healthcare provider to be certain that they will not damage their livers.
- Determine hepatitis A or B immunization status. If not immunized, provide information on hepatitis A and hepatitis B immunization. (Refer to the Hepatitis A and Hepatitis B disease plans for more information.)
- Inform the case that he/she should not be restricted from working, preparing food, or taking part in their daily activities unless they have specific symptoms that make it difficult to do so. There are no recommendations suggesting that HCV-infected persons should change their exercise routines or have any dietary restrictions.
- Encourage them to consult with their healthcare provider, or suggest involvement in a research study. Research facilities conduct clinical trials on hepatitis medications and are often looking for individuals to participate. For further information on current trials and qualifications, visit www.clinicaltrials.gov. Local agencies that have a history of HCV Medication Clinical trials include: The University of Utah Medical Center (http://healthcare.utah.edu/clinicaltrials), and Jean Brown Research (https://www.jbrclinicalresearch.com or contact the UDOH Bureau of Epidemiology, Prevention Treatment and Care Program (PTCP) at 801-538-6191 for additional resources.

Appendix D: Local Health Department Action Steps

This quick reference guide is designed for local health departments (LHDs) to use for HCV case investigation activities and is a suggested sequence of investigation and information that should be reviewed with each case. This guidance corresponds with the investigation algorithm included below.

Upon receiving a report of acute HCV infection from UDOH, a laboratory, or a healthcare provider, please follow the process detailed below:

1) Decide if report meets investigation criteria:
    - Anti-HCV antibody positive from an acute hepatitis panel
    - HCV detection test from donor screening
    - HCV+ suspect acute - based on circumstantial evidence and/or health department discretion
    - Co-infected (HIV/AIDS, HBV), if not previously investigated

2) Call or fax a request for ALT, Tbili, or last negative donation result from the lab or Donation Center respectively. The following are criteria for moving to step 3 (or 4):
    - ALT >200 IU/L
    - Tbili >3.0 mg/dL
    - Negative HCV <12 months **(move directly to step 4)**

3) Request medical records to review clinical presentation. The following are criteria for moving to step 4:
    - Co-infected (HIV/AIDS, HBV), if not previously investigated, **OR**
    - Jaundice, **AND**
    - Absence of other etiologies/underlying conditions to explain clinical elevated LFT, Tbili

If the investigation criteria are not met, no investigation is needed.
For individuals that meet the investigation criteria, proceed with investigation.

4) Contact case for full investigation as described:
    - Complete form (risk factor) questionnaire
    - Attempt to identify place exposure and contacts
    - Assist with education to disrupt transmission

Hepatitis C Investigation Algorithm